



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,452	12/30/2003	Michael J. Bonnette	POSSIS	2399
21270	7590	10/19/2005	EXAMINER	
HUGH D JAEGER 1000 SUPERIOR BLVD SUITE 302 WAYZATA, MN 553911873			JOHNSON, JERROLD D	
			ART UNIT	PAPER NUMBER
			3728	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8

Office Action Summary	Application No.	Applicant(s)	
	10/748,452	BONNETTE ET AL.	
	Examiner	Art Unit	
	Jerrold Johnson	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims 1-8 and 10 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 9,11-13,19-22 and 23 are rejected under 35 U.S.C. as being anticipated by or in the alternative under 35 U.S.C. 103(a) as being unpatentable over George US 5,014,494.

Re claim 9, George provides a plastic/foil laminate sealable container storage arrangement for oxygen-sensitive plastic medical articles that need to undergo gamma radiation in the absence of oxygen, lest they also be subject to deterioration through yellowing. George discloses the isolation of the medical article from ambient atmosphere while the article is in the container. And, George discloses several polymer plastics by example which are known to yellow post gamma radiation. For those plastics that yellow in the presence of oxygen post gamma radiation, yellowing will occur in the package of George should the package be opened within the time window that the plastic is sensitive to oxygen. Additionally, George impliedly suggests that more than one oxygen sensitive article be disposed in the container. See the use of "articles" throughout the disclosure, and claim 6. Accordingly, George inherently discloses both an oxygen sensitive product, and an oxygen-sensitive material which provides a visual oxygen sensing indicator (another oxygen-sensitive medical article), or at the very least it would be obvious to one of ordinary skill in the art to provide two or more articles in the storage arrangement of George in response to the teachings provided within his patent.

With respect to Applicant's arguments that George does not disclose the material being activated once the oxygen-sensitive material has been irradiated as is claimed, this is exactly the type of materials to which George is directed. Applicant suggests that George will experience rapid and premature yellowing "within minutes" during a gamma sterilization procedure. If so, then Applicant also admits that George discloses the post radiation activation and yellowing in the presence of oxygen that is claimed.

It is further noted that the claim is presented in a product-by-process form. Claims of this type are not limited by the process steps, only by the structure implied by those steps. See MPEP 2113. Claim 9 implies a structure is activated to undergo a visual change when in contact with oxygen subsequent to radiation. George clearly discloses this structure.

Re claim 11, another medical device other than the first device meets this language.

Re claim 12, George further inherently discloses a storage arrangement wherein wherein the visual change of the oxygen-sensitive material indicates a failure of the sealable container. Specifically, if the container has failed and oxygen is let into the container, yellowing will occur in those plastics disclosed by George which yellow in the presence of oxygen post gamma radiation.

Re claim 13, George discloses various polymer plastics by way of example in col. 2, lines 28 and 29.

Re claim 19, note the Applicant's admission of "within minutes". Within minutes is within 8 hours.

Re claim 20, note the Applicant's admission of "within minutes". Within minutes is within 1-2 hours.

Re claim 21, George discloses medical devices.

Re claim 22, the color change formed on the medical device is the symbol that assists in interpreting the visual change.

Re claim 23, George discloses a purged "oxygen poor" atmosphere, along with the other claimed features set forth in claim 9 rejected above.

2. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over George US 5,014,494 in view of Sleenckx US 6,166,116.

George discloses by example several plastics which are known to yellow post gamma radiation, but does not identify polycarbonate specifically.

The prior art is replete with different polycarbonate compositions each of which have been formulated to minimize the yellowing which occurs as a result of the common practice of gamma sterilization. Many of these formulations have high sensitivity to the presence of oxygen post gamma sterilization, and therefor must be sterilized in an oxygen free environment. Funakoshi et al. US 6,485,657 provides extrinsic evidence of this fact in col. 2, paragraph 1. DeRudder et al. US 5,196,245, in col. 8 lines 46-60 further evidences this fact.

Sleenckx, in col. 9, lines 14-32, discloses such a polycarbonate formulation. Note that there is a typo in this recitation, specifically, "absence" in line 16, clearly should be "presence". Col. 10 lines 29+ provides an example of the testing performed in the absence of oxygen.

It would have been obvious to one of ordinary skill in the art to have used the sealable container of George with the polycarbonate plastic disclosed by Sleenckx, so as to properly shield the polycarbonate of Sleenckx from oxygen during the sterilization process to minimize yellowing.

3. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over George US 5,014,494 in view of Nicolais US 6,161,695, Ahlqvist et al US 5,881,534 and Examiner Official Notice.

George does not explicitly set forth the plastic/foil laminate as set forth in claims 16 and 17, but does disclose in col. 2, line 47, impermeable containers using foil which are necessary for the sterilization in the absence of oxygen.

Nicolais, discloses a gas-impermeable foil pouch having a polymer/foil construction (the well known construction of impermeable pouches) and an outer cardboard protective packaging. Nicolais does not disclose the exact foil pouch laminate as set forth in claim 17. However, it is submitted that this laminate is known in the prior art, as there are literally hundreds of such laminates used in the medical industry. And, Applicant devoted a single sentence to this laminate, which suggests that this laminate is merely an off the shelf laminate known in the art.

Ahlqvist discloses in col. 8 lines 1-12 laminates having PET layers, and the known irradiation dose of 35 kGy, which is a common radiation dose used in sterilization of medical devices.

Accordingly, it would have been obvious to modify the container of George with the teachings of using a multiple medical devices in the sealed container during sterilization, so that if oxygen is present and the device yellows, the situation will be easily visually identified.

Additionally it would have been further obvious to have used a gas-impermeable foil pouch within a cardboard packaging, as disclosed by Nicolais, as such foil pouches are known for their impermeability to air, a necessity set forth by George, and to protect the pouch with a cardboard packaging to protect the foil pouch from puncture.

With respect to claim 15, it would be obvious to use a range for the amount of gamma radiation from 25 kGy to 45 kGys as disclosed by Ahlqvist, as that is the range commonly used to sterilize medical devices, and is within the capabilities of the equipment already used for this purpose.

With respect to the specific laminate set forth in claim 17, the Examiner submits that such a laminate is well known in the art. For economic reasons, it would be obvious to use a known polymer foil laminate in the construction of the pouch.

4. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlqvist et al US 5,881,534 in view of Komatsu et al. US 4,166,807.

Ahlqvist discloses the storage arrangement of a sealable container, an oxygen-sensitive product, and an oxygen sensitive material (iron based oxygen scavenger). The iron based oxygen scavenger inherently is activated both before and after radiation, and iron based oxygen scavengers clearly undergo a color change as the iron becomes iron oxide (see also US 6,927,063 herein cited as extrinsic evidence of the color change in iron based oxygen scavengers). Again note that the product-by-process claim limitation is met by a product having the implied structure of being activated to undergo a color change in the presence of oxygen after radiation. The iron oxygen scavenger of

Art Unit: 3728

Ahlqvist would be activated to undergo a color change both before and after radiation, and accordingly meets the product-by-process claim limitation.

Ahlqvist does not disclose the oxygen-sensitive material being in a chip form.

Komatsu in claim 6 describes iron based oxygen scavengers in chip form.

Accordingly, it would have been obvious to one of ordinary skill in the art to modify the storage arrangement of Ahlqvist with the teaching of Komatsu so as to provide the oxygen sensitive material in a form that takes little space in the package.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ



Mickey Yu
Supervisory Patent Examiner
Group 3700